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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,446	03/04/2002	Clara L. Garcia-Rodenas	112843-027	4113

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/936,446	Garcia-Rodenas et al.
Examiner	**Art Unit**
Randall Winston	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-24 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on December 9, 2002.

Claims 1-24 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1- 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Since the limitation in claims 1, 7, 13 and 19 of the broad term "including"does not appear to be disclosed within the specification and, thus, is deemed new matter, it is strongly suggested to applicants that the broader term "including" should be changed to "in the form of" according to what applicants have disclosed in it specification. (Note: please, see 112, second paragraph, for a further explanation)

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a composition and/or methods of a whey dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids for favoring the growth and

maturation of non-maturation of non-mature gastro-intestinal tracts of young mammals, the specification does not enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and/or use the invention commensurate in the scope of the claims. The specification does not enable any person skilled in the art to utilize any and/or all forms of dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids whereby any and/or all forms of dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids could be utilized for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals.

Applicants have reasonably demonstrated a composition and/or methods of a whey dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids for favoring the growth and maturation of non-maturation of non-mature gastro-intestinal tracts of young mammals. Applicants, however, fail to provide any working examples whereby any and/or forms of dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids could be utilized for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals. Accordingly, it would take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a composition and/or methods whereby utilizing any and/or all forms of dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids because it is clearly beyond the scope of the instantly demonstrated working examples.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards fas the invention.

Claims 1, 7, 13, and 19 are rendered vague and indefinite by the phrase "dietary protein hydrolysates including a mixture of different size peptides and free amino acids," because the metes and bounds of the term "including" are not clearly delineated. (e.g., the term including implies that the dietary protein hydrolysates mixture of different size peptides and free amino acids could also include other active ingredients therein) Please note, applicants have only provided working examples for a "whey dietary protein hydrolysates" and applicants have only disclosed within its specification the closed language of "the form of" instead of the broader/open language of "including." Accordingly, it is suggested that applicants amend this phrase so as to recite --whey dietary protein hydrolysates in the form of a mixture of different size peptides and free amino acids.--

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. (US 4,977,137).

Applicant argues that the primary focus of the Nichols reference relates to a single dietary ingredient, namely milk lactoferrin. Clearly, this suggests that Nichols considers milk lactoferrin to be "a sole growth promoter sufficient to promote gastrointestinal tract growth in human infants and infant animals." Applicant argument, however, is not found persuasive because Nicoles expressly teaches that (see, e.g. column 2 lines 53-56) intact proteins, such as milk, intrinsically contains biactive peptides, epidermal growth factors, to promote gastrointestinal tract growth in human infants and animals. Thus, one of ordinary skill in the art would have been motivated to modify Nicholes teachings (even if Nicholes teaches milk lactoferrin being the sole promoter) to include the expressed teaching taught in therein(see, e.g., column 2 lines 53-56) to create the claimed invention.

Furthermore, applicant argues that Nichols fails to disclose the specific ranges and ratios of the ingredients of the nutritional composition as required by the claimed invention as even

admitted by the Patent Office. Applicant argument, however, is not found persuasive because since the reference clearly indicates that the various proportions and amounts of the claimed composition and method are result effective variables and, thus, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by the reference.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER